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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,028	12/14/2004	Giancarlo Rizzoli	2579.01 IUSI	4654

21186 7590 06/23/2009
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EXAMINER

BARHAM, BETHANY P

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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06/23/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
scape@slwip.com

Office Action Summary

Application No.

10/510,028

Applicant(s)

RIZZOLI ET AL.

Examiner

BETHANY BARHAM

Art Unit

1615

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9, 10, 17, 21, 26 and 28-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-6, 9, 10, 17, 21, 26 and 28-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

It is noted that Applicant's reply on 1/29/09 is non-responsive. Applicant is required to elect a calcium containing ceramic particle (i.e. dicalcium phosphate dehydrate) and a hydrogel (i.e. glycosaminoglycane) (claims 32-39 and 43) and the properties that read on the elected species must be identified (water content (claims 44-45), molecular weight (claims 41-42 and 46-48), weight relationship of A/B (claims 51-56)) for examination purposes. It is noted that this case has been transferred from Examiner Tristan Mahyera to Examiner Bethany Barham, as such the election of species has been amended to include C) ceramic particles (i.e. calcium carbonate).

Election/Restrictions

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species that form the "kneadable and moldable bone-replacement material" are as follows:

A) calcium containing ceramic particles (i.e. dicalcium phosphate dehydrate, etc) of claim 1.

B) a hydrogel (i.e. glycosaminoglycane, etc) (claims 32-39 and 43) and the properties that read on the elected species must be identified (water content (claims 44-45), molecular weight (claims 41-42 and 46-48), weight relationship of A/B (claims 51-56)).

C) ceramic particles (i.e. calcium carbonate, etc) of claims 28-30.

Applicant is required, in reply to this action, **to elect a single species (A, B, and C) to which the claims shall be restricted if no generic claim is finally held to be allowable**. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-6, 9, 10, 17, 21, 26 and 28-56.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The special technical feature is not novel. The common technical feature is claim 1 comprising a non-spherical synthetic porous ceramic particle and a hydrogel. A common technical feature known in the art, as is the case here, cannot be a special technical feature. The prior art, e.g. DORIGATTI et al. (WO 93/20858 see PTO/SB/08) teach the use of hyaluronic acid in combination with artificial porous bone granules in a moldable paste to promote growth and repair of damaged bone tissue. See e.g. abstract, page 6 line 33 to page 7 line 3. While DORIGATTI does not explicitly state non-spherical shapes BEARCROFT et al. (WO 01/66044 see PTO-892) teaches a shaped particle that is non-spherical to repair a bone deficiency whereby the non-spherical shape facilitates interlocking of adjacent particles in a matrix of shaped particles. See e.g. page 8 lines 1-24. Therefore, the technical feature of the groups do not make a contribution over the prior art.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement

may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BETHANY BARHAM whose telephone number is (571)272-6175. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bethany Barham/
Examiner, Art Unit 1615

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635